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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,453	11/28/2003	James C. Peacock III	53233-00007	9909

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EXAMINER	
DOWE, KATHERINE MARIE	

ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
02/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/724,453	PEACOCK, JAMES C.	
	Examiner	Art Unit	
	KATHERINE M. DOWE	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8,9 and 11-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,8,9 and 11-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a complete response to the amendment filed September 21, 2009.

2. Claims 2-6, 8, 9, and 11-46 are currently pending.

Claim Rejections - 35 USC § 112

3. Applicant's arguments, see amendment, filed September 21, 2009, with respect to the rejection of claims 8, 9, and 29-33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, have been fully considered and are persuasive. The rejection has been withdrawn.

4. Applicant's arguments, see amendment, filed September 21, 2009, with respect to the rejection of claims 29-33 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, have been fully considered and are persuasive. The rejection has been withdrawn.

5. Applicant's arguments, see amendment, filed September 21, 2009, with respect to the rejection of claims 2-11 and 16-43 under 35 U.S.C. 112, second paragraph, as being indefinite, have been fully considered and are persuasive. The rejection has been withdrawn.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 2-5, 8, 9, 11, 17, 29, 34-37, 39, and 44 are rejected under 35 U.S.C. 102(a) as being anticipated by Vallana et al. (US 2003/0125803, hereinafter "Vallana"). Regarding claims 2 and 44, Vallana discloses an endolumenal stent system comprising an endolumenal stent (2) and a porous surface on the endolumenal stent comprising a first material (5) co-deposited with a second composite material (1) that is different from the first material such that the first material forms a plurality of pores and the second material forms a plurality of discrete particles within the pores (Fig 6; ¶0017). The second composite material (Fig 1; ¶0043-0044) comprises a bioerodible material (1b; ¶0094, 0098) in combination with a bioactive agent (1a; ¶0045). The discrete particles of the second composite material (1) comprise an outer diameter and the pores of the first material (5) comprise an inner diameter, wherein the inner diameter is substantially equivalent to the outer diameter since the particles are located within the pores (Fig 6).

Regarding claims 3-5, 8, and 9, the particles comprise an outer diameter that is less than about 1 micron and the pores comprise an inner diameter that is greater than about 1 micron and less than about 5 microns (¶0012).

Regarding claim 11, the first material (5) is inherently porous since it forms pores around the second composite material (1) when the materials are co-deposited on the stent surface (Fig 6).

Regarding claim 17, the endolumenal stent comprises a scaffold (2) constructed from a third material, the first material (5) is a coating located on and in contact with the third material, and the pores are located within the first material (Fig 6).

Regarding claim 29, the first material may alternatively be interpreted as the top polymeric matrix layer (5') such that the endolumenal stent comprises a scaffold (2) constructed from a third material, a fourth material (5) is provided on the third material, and the first material

(5') comprises a coating on the scaffold with the fourth material located between the first material and the third material (Fig 8).

Regarding claims 34-37 and 39, the bioactive agent may comprise an anti-restenosis agent, an anti-inflammatory agent, an anti-proliferative agent, a steroid or a combination thereof (¶0045-0081).

Further regarding claim 44, the composite particles (1) are adapted to release the bioactive agent (1a) and the bioerodible material is adapted to erode from the coating material to thereby leave a plurality of voids in the remaining coating material (5) when the endoluminal stent is implanted within the body of a patient (¶0098, 0117).

Claim Rejections - 35 USC § 102/103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over O'Brien et al. (US 2005/0060021, hereinafter "O'Brien"). Regarding claim 12, O'Brien discloses a stent system (Fig 2A) comprising an endolumenal stent (20) and a porous surface (24) on the endolumenal stent comprising a first material (26) having a plurality of pores (27, 28). A second composite material that is different from the first material is located within each of the pores and comprises a bioactive agent (30) in combination with a bioerodible polymer material (¶0060). The first material (26) is not inherently porous and the pores are formed at discrete locations within the first material along the surface (Fig 2A).

Regarding claims 13-15, the claimed phrase "wherein the pores are…" is being treated as a product by process limitation; that is, the pores are formed by laser cutting, photochemical

etching, or chemical etching. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113. The endolumenal stent system of O'Brien et al. appears to be substantially the same product as claimed as shown above.

10. Claim 46 is rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vallana (US 2003/0125803). Vallana discloses a system for depositing a bioactive coating onto a surface of an endoluminal stent (2) comprising a plurality of discrete composite particles (1) located within a coating environment, wherein the particles comprise a bioerodible material (1b) in combination with a bioactive agent (1a). The coating environment additionally includes a coating precursor material that will form the first coating material (5) such that the coating environment is adapted to co-deposit a coating material (5) from the precursor material in combination with the discrete composite particles (1) onto the surface so as to form a structurally co-deposited composite surface coating that is adapted to release the bioactive agent (1a) and erode the bioerodible material (1b) from the coating material that remains on the surface when the coated surface is exposed to a body of a patient. Alternatively, it would have been obvious that a system for depositing the bioactive coating onto the surface of the endolumenal stent comprised a precursor material that will form the first coating material (5) since it is well known that polymeric matrices are formed with a precursor material in the coating environment that is solidified once it is deposited as desired.

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 6, 16, 18, and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallana (US 2003/0125803), as applied to claim 17 above. Regarding claims 6 and 43, Vallana discloses the invention substantially as claimed as shown above. Vallana discloses the particles comprise a bioerodible material (1b; ¶0094, 0098), however he does not disclose the bioerodible material is a polymeric material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Vallana such that the bioerodible material of the second composite material was a bioerodible polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claims 16 and 18, Vallana discloses the first coating material (5) is a polymeric material and does not disclose the material may be non-polymeric or sintered. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Vallana such that the first material was non-polymeric or sintered, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claims 40-42, Vallana does not disclose the specific ratio of the bioactive material (1a) to bioerodible material (1b) in the composite material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Vallana such that the ratio of bioactive material to bioerodible material was at least about 0.5:1,

since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

13. Claims 18-28, 30-33, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallana (US 2003/0125803), as applied to claim 17 above, in view of Gertner et al. (US 2003/0060873, hereinafter "Gertner"). Regarding claims 18-23, 26, 27, and 45, Vallana disclose the invention substantially as claimed as shown above including an endolumenal stent surface (2) with a first porous coating material (5) and second composite material forming a plurality of particles (1) structurally co-deposited to the surface of the stent, such that the first coating material forms a plurality of pores around the plurality of particles (1). However, Vallana discloses the first coating material is a polymeric material and thus does not disclose the coating environment comprises a plurality of metal ions as the precursor to the first coating material or that the first coating material comprises an electrolessly electrochemically deposited material. Gertner discloses a similar device including a stent comprising a scaffold, a porous surface on the stent comprising a first material and a plurality of pores, and a second material comprising a bioactive agent located within the pores formed by co-depositing the first and second materials (¶0047-0068). The first material is an electrolessly electrochemically deposited metallic matrix (¶0048) and thus comprises a metal and a reducing agent of the metal (¶0036, 0057). The metal may comprise nickel or cobalt and the reducing agent may comprise phosphorus (¶0056, 0064). Gertner teaches an electrolessly electrochemically deposited metallic coating material is advantageous over a polymeric coating material for delivering a bioactive agent from a stent to better predict the degradation Kinetics, reduce possible inflammatory responses, improve the adherence of the coating to the stent surface, and more evenly coat the coating material on the

stent surface (¶0008). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Vallana such that the polymeric matrix (5) was replaced with an electrolessly electrochemically deposited material as taught by Gertner, wherein the discrete particles (1) are structurally co-deposited with the metal ions of the electrolessly electrochemically deposited material to form the porous coating layer with the discrete particles within the pores of the coating layer.

Regarding claims 24, 25, and 28, Vallana does not disclose the composition of the stent third material (2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Vallana such that the stent third material comprised a stainless steel alloy, a nickel-titanium alloy, or a cobalt-chromium alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claims 30-33, Gertner teaches a fourth material may be formed between the stent, or third material, and the coating, or first material, and a fifth material may be formed between the fourth material and the coating, or first material, since a plurality of layers may be formed with coating layers between metallic layers (¶0063). The fourth material may be electroplated metal such as nickel (¶0029, 0036, 0064), the fifth material may be a layer of electrolessly electrochemically deposited composite with metal and a reducing agent of the metal (¶0056-0058), and the coating, or first material, may be another layer of electrolessly electrochemically deposited composite with metal and reducing agent of the metal with the composite material (¶0051). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Vallana such that the stent system comprised a fourth layer of electroplated nickel and a fifth layer of electrolessly

electrochemically deposited material comprising a metal and its reducing agent between the stent, or third material, and the first material. Furthermore, it would have been obvious to modify the first coating material such that it was composed of an electrolessly electrochemically deposited material comprising a metal and its reducing agent. The additional layers would provide additional pores to provide a greater amount of bioactive agent. Furthermore, the electroless electrochemical deposition would allow the Vallana device to incorporate the benefits of a metallic drug delivery coating taught by Gertner (¶0008), as discussed above.

14. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vallana (US 2003/0125803), as applied to claim 2 above, in view of Wang et al. (US 2007/0037739, hereinafter "Wang"). Vallana discloses the invention substantially as claimed as shown above. However, Vallana does not disclose the bioactive specifically comprises des-aspartate angiotensin 1. Wang discloses compounds useful in coating stents to treat restenosis including des-aspartate angiotensin 1 (¶0040, 0253-0261), which has been shown to substantially inhibit smooth muscle cell proliferation and drastically reduce restenosis (¶0261). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Vallana such that the bioactive agent comprised des-aspartate angiotensin 1 to more effectively reduce restenosis.

Response to Arguments

15. Applicant's arguments, see amendment, filed September 21, 2009, with respect to the rejection(s) of claim(s) 2-6, 8, 9, 11, and 16-46 under O'Brien (US 2005/0060021) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However,

upon further consideration, a new ground(s) of rejection is made in view of Vallana (US 2003/0125803) and Gertner (US 2003/0060873).

16. Applicant's arguments filed September 21, 2009, with respect to the rejection(s) of claims(s) 12-15 under O'Brien (US 2005/0060021) have been fully considered but they are not persuasive. Applicant argues O'Brien does not teach a plurality of pores, but rather teaches a plurality of voids that serve as wells or depots for therapeutic material. The Examiner respectfully notes pores are commonly defined as voids such that the therapeutic material, or second composite material, may be located within each of the voids. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. It is not clear how a void is structurally distinguished from a pore.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
January 29, 2010

/K. M. D./
Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734